REMARKS

The section 112, first paragraph, rejections

Applicants respectfully disagree with the lack of written description rejection regarding the proviso in claim 1, but nevertheless decided to amend the claims without the use of provisos to further the prosecution of the application.

Claim 1 is amended. The proviso is removed. The definitions of R^{20} and R^{20a} are amended whereby hydrogen is removed from the groups these substituents represent.

Claim 8 is amended to be a compound claim. The definition of R^{10} is amended to a hydrogen atom or an ethyl, propyl, isopropyl, butyl, isobutyl, or tert-butyl group. Support can be found, for example, on page 3, in the 4th paragraph of the specification.

Claim 10 is amended to be a compound claim. The definition of R^4 is amended to a fluorine, bromine, or iodine atom or a pseudohalogen. Support can be found, for example, on page 3, in the 3rd paragraph of the specification.

Claim 11 is amended to be a compound claim. The definition of R^{20} and R^{20a} are independently defined. Hydrogen is removed from the groups R^{20a} represents.

Claim 12 is amended to be a compound claim. R^4 is defined as a pseudohalogen.

Claims 13, 16, 17, and 18 are amended to pharmaceutical composition claims and depend from claims discussed above.

Claim 20 is now directed to a method of treating a prostate disease.

Applicants also respectfully disagree with the enablement rejection of the method of use claims, but nevertheless decided to amend the claims to further the prosecution of the application.

The only method of use claims remaining after the amendments are claims 20, 21 and 22. These use claims all depend from claim 5, which claims 13 specific compounds.

A rejection over the utility of a claimed compound should not be couched in a rejection under 35 USC § 112, first paragraph, but as a rejection over the practical utility under 35 USC § 101, or at most as an enablement rejection in conjunction with a practical utility rejection.

A deficiency under 35 U.S.C. § 101 can also create a deficiency under 35 U.S.C. 112,

first paragraph, because " [t]he how to use prong of section 112 incorporates as a matter of law the requirement of 35 U.S.C. Section 101 that the specification disclose as a matter of fact a practical utility for the invention," see *In re Ziegler*, 992 F.2d 1197, 1200, 26 USPQ2d 1600 (Fed. Cir. 1993), or because, as stated otherwise, if a claimed invention does not have utility, the specification cannot enable one to use it. See *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1441 (Fed. Cir. 1995). However, the converse is not true. MPEP 35 § 2107 is in agreement with the above-cited decisions and states that "Office personnel should not impose a 35 USC § 112, first paragraph, rejection grounded on a 'lack of utility' unless a 35 USC § 101 rejection is proper." The Examiner, contrary to the guidance of the law and the MPEP, makes a section 112 rejection and provides reasons consistent with a section 101 rejection without making a section 101 rejection, thereby imposing a higher burden on applicants to overcome the rejection. "The PTO cannot make this type of rejection [court discussing combined section 101 an 112, first paragraph, rejection], however, unless it has reason to doubt the objective truth of the statements contained in the written description." See *In re Cortright*, 49 USPQ2d 1464 (CAFC 1999), citing *Brana*, supra. Since there is no section 101 rejection, the allegations are improper and/or irrelevant under section 112, first paragraph. For this reasons alone, the rejection should be withdrawn. Nevertheless the allegations are discussed below.

In an enablement rejection, first and foremost, a specification disclosure which "contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." *In re Marzocchi*, 169 U.S.P.Q. 367, 369 (1971). "The PTO must have adequate support for its challenge to the credibility of applicant's statements of utility". (The quoted statement was made in the context of enablement, i.e., the how-to-use requirement of the first paragraph of section 112.) See also *In re Bundy*, 209 USPQ 48 (1981). The only relevant concern of the Patent Office should be over the truth of assertions relating to enablement. The first paragraph of section 112 requires nothing more than objective enablement. See *In re Marzocchi, supra.*

The Examiner has not established any basis to doubt objective enablement. The Examiner has also provided no support for establishing that one of ordinary skill would doubt the objective

truth of the asserted utility, which is enabled by the specification. The enablement rejections by the Examiner are thus unfounded. The rejection therefore was improper under *In re Marzocchi.*

The claims rejected are directed to the treatment of prostate diseases (claim 20), to effecting contraception (claim 21), and to inhibiting 5α-reductase (claim 22), i.e., to treatments, effects and activities that are not objectively doubtable. Doubt has been held reasonable only where, for example, the invention has been characterized as "highly unusual," *In re Houghton*, 433 F.2d 820 (CCPA 1970), as "incredible," *In re Citron*, 325 F.2d 248, (CCPA 1963), or as "too speculative," *In re Eltgroth*, 419 F.2d 918 (CCPA 1970). Because compounds having similar therapeutic activities are known in the art, the existence of a new class of compounds having the claimed activities is not objectively doubtable, i.e., not "highly unusual," "incredible," and/or "too speculative."

Even if the asserted utilities would be objectively doubtable, which they are not, applicants provide adequate guidance in the specification for one of ordinary skill in the art as to how to proceed in using the claimed invention.

Applicants teach that "compounds according to the invention have a hybrid-type profile of action. They are inhibitors of 5α-reductase and, moreover, also act as gestagens. They are therefore suitable for treating diseases that are the result of elevated androgen levels in certain organs and tissues in men and women." See page 8, 3rd paragraph. The specification on page 8, 4th paragraph states that "The simultaneous presence of a gestagenic action in compounds according to the invention results in an inhibition of gonadal function in males and females. This effect is desirable if an antifertile action or else an inhibition of the hormone secretion of the gonads is to be achieved with the treatment. This is frequently the case in diseases of the prostate (benign prostate hyperplasia)." On page 9, first two paragraphs, the specification teaches that the compounds of the invention can be used as contraceptives.

Additionally, applicants provide guidance as to how the activities of the compounds can be determined by demonstrating in an example in genital germal homogenates the 5α-Reductase-Type 2-Activity of a compound according to the invention. See table 1 on page 11. Applicants also provide *in vivo* data for gestagenic activity of the same compound. See table 2 on page 11. One of ordinary skill in the art through routine testing of the compounds, can determine the activity level of each of the 12 remaining compounds subject of the method claims.

As discussed above, this is adequate to objectively enable an invention. Without proper

reason or evidence to doubt the objective truth of the enabling disclosure, the Examiner improperly requires evidence to prove utility and/or to support enablement. "Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility." *See In re Bundy*, supra. The burden has not been shifted.

With regard to *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988), used by the Examiner as the basis of the rejections, the court therein teaches that whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations. Factors to consider whether a disclosure requires undue experimentation is summarized to include the 8 *Wands* factors (not reproduced here). No factor alone is determinative. The court in *Wands*, further held that the test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. Applicants have provided adequate guidance.

Nevertheless, applicants address the allegations with respect to the Wands factors.

The nature of the invention with respect to the rejected claims is the use of 13 specific compounds for a variety of related indications.

With respect to the predictability in the art, the Office Action alleges that the unpredictability in the art of steroids is very high. No support for this allegation is provided by the Office Action.

The Office Action further alleges that it would require a "case to case ... painstaking experimental study" to determine the activity levels of the claimed compounds. As discussed in *Wands*, supra, "considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." Here, the specification provides assay data on activity and *in vivo* data for one of the 13 compounds whose utility the method claims are directed to. In a similar fashion, one of ordinary skill in the art by performing the same or similar tests, can, by routine experimentation, determine the activity levels of the remaining 12 compounds. While this may, although not admitted to be, "painstaking," the test for lack of enablement is whether such experimentation is "undue," which it is not.

With respect to the breadth of the claims, the Office Action alleges that the claims are very broad, especially the method claims. The compounds whose use is claimed are the 13 compounds recited in claim 5. The methods are directed to indications related by the activities of the compounds as discussed above. See, for example, the specification on pages 8 and 9.

The Office Action alleges that the specification provides "no guidance" in the way of written description. Contrary to this allegation, applicants provide guidance in the type of activities possessed by the compounds and actually provide experimental data for one of the 13 claimed compounds whose use is claimed. Written description to the entire claimed subject matter can be found in the specification.

The Examiner's reliance on *In re Dreshfield*, 110 F.2d 235, 45 USPQ 36 (CCPA 1940) is misplaced. *Dreshfield* does not involve an enablement rejection of method of use claims, or as a matter of fact of any type of claims. The claims involved were compound claims that were broader than the original disclosure and were rejected for being broader than the original disclosure. See holding, i.e., "we are of the opinion that claims 15, 16, and 17 were properly rejected by the Primary Examiner on the ground that they are broader than appellant's original disclosure." Claims 15, 16, and 17 were the claims that were rejected by the Examiner as containing antioxidants whose "effectiveness ... could be determined only by experiment." The term antioxidants were conceded by appellant's counsel to contain antioxidants used in a large number of industries. Additionally counsel conceded that "both the physical and chemical nature of the materials under consideration differs so markedly from materials in other industries where anti-oxidants were known to be needed." No evidence of any of these type of facts are present in the current case.

Additionally, as a side note, the language referred to by the Office Action from *Dreshfield* has been limited by later decisions. See, for example, the CCPA stating that "it may not be necessary to enumerate a plurality of species if a genus is sufficiently identified in an application by "other appropriate language." See *In re Grimme*, 247 F.2d 949, 124 USPQ 499 (CCPA 1960), discussing *Dreshfield*.

The present situation is different than *Dreshfield*. The method of use claims depend from an allowed compound claim. Additionally, said allowed claim contains 13 specifically named species, one of whose activity is tested by an assay and also *in vivo*. The remaining compounds likewise can be tested by routine experimentation. The utilities to which the methods are directed are disclosed in

the specification. The claims are thus, not broader than what is disclosed.

The Office Action states that the disclosure contains only one example. This example demonstrates two separate tests on one of the compounds, i.e., one assay and one *in vivo* tests. The remaining 12 compounds can likewise be tested. The Office Action offers no evidence or reasoning why the example would not be representative and sufficient.

Instead the Office Action cites to *In re Shokal*, 242, F.2d 771, 113 USPQ 283 (CCPA 1957) and *In re Grimme*, supra, for the proposition that a single species is seldom sufficient to support a generic claim. However, the allegation is irrelevant to the present situation. The cited cases do not deal with method of use claims of otherwise allowed specific compounds. Instead they deal with the situation where only one compound is named in the application, and at the same time a generic claim is prosecuted. Here, applicants have a claim that is directed to 13 compounds, which are clearly identified by name in the specification. The compound claims, including some generic claims are already allowed. The rejection does not even involve a generic claim as the method of use claims are directed to the use of the specific compounds of claim 5.

Additionally, there is no requirement for any examples. See, for example, *Marzocchi*, supra, stating that "an enabling teaching is set forth, either by use of illustrative examples or by broad terminology, is of no importance." The MPEP in agreement by stating that "compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed." See MPEP § 2164.02.

The Office Action also cited *In re Tiffin*, 171 USPQ 294 (CCPA 1971) and alleges that a showing limited to a single species can hardly be considered probative of an invention's nonobviousness in view of the breadth of the claims. This allegation is also irrelevant to the situation. This is not an "obviousness" rejection, but a section 101, first paragraph, enablement rejection. In *Tiffin*, the applicants claimed *prima facie* obvious subject matter and their rebuttal evidence of unexpected results was limited to a single species which was not adequate to overcome the obviousness rejection.

Applicants point to *Bundy*, supra, where the specification stated that the compounds of the invention possess activity similar to E-type prostaglandins, but provided **no** examples. Nevertheless the court found that sufficient guidelines as to use were given in the disclosure. The court held that "what is necessary to satisfy the how-to-use requirement of section 112 is the disclosure of some

activity coupled with knowledge as to the use of this activity."

Applicants provided adequate support and evidence to enable the method claims. Thus, reconsideration of the rejection is respectfully requested.

It is submitted that the claims are in condition for allowance. However, the Examiner is kindly invited to contact the undersigned to discuss any unresolved matters.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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